

In re Application of: Tamar HAREL et al  
Serial No.: 10/526,708  
Filed: September 20, 2005  
Office Action Mailing Date: July 14, 2008

Examiner: FLORY, Christopher A.  
Group Art Unit: 3762  
Attorney Docket: 34490

**In the Claims:**

1. (Currently amended)      A method of glucose level control, comprising:  
  
        providing at least one implanted electrode ~~adapted to~~ for applying an electric field to affect a pancreas; and  
  
        applying an electric field to affect the pancreas using said at least one implanted electrode such that blood glucose levels are significantly reduced and blood insulin levels are not significantly increased.
2. (Currently amended)      A method according to claim 1, comprising subsequently applying a second electric field to affect said pancreas, which second field increases insulin levels.
3. (Original)      A method according to claim 1, wherein said electric field is operative to reduce glucagon secretion.
4. (Original)      A method according to claim 1, wherein said electric field is operative to reduce glucose secretion by a liver physiologically coupled to said pancreas.
5. (Original)      A method according to claim 1, wherein said electric field is operative to increase glucose uptake by cells in a body containing said pancreas.
6. (Original)      A method according to claim 1, wherein said electric field is operative to affect nervous tissue in said pancreas.

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7. (Original) A method according to claim 1, wherein said electric field is non-excitatory in that it does not substantially induce new bursts of islet activity in said pancreas.
8. (Original) A method according to claim 1, wherein said electric field is applied as a bi-phasic and charge balanced time varying field.
9. (Original) A method according to claim 8, wherein said electric field is applied for a short duration every period of time.
10. (Original) A method according to claim 9, wherein said period of time gives an application frequency of between 1Hz and 15 Hz.
11. (Original) A method according to claim 9, wherein said period of time gives an application frequency of about 5 Hz.
12. (Original) A method according to claim 9, wherein said duration is less than 30 ms.
13. (Original) A method according to claim 9, wherein said duration is about 10 ms.
14. (Original) A method according to claim 1, wherein said electric field is repeated for a period of less than 30 minutes.

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15. (Original) A method according to claim 1, wherein said electric field is repeated for a period of between 30 and 180 minutes.

16. (Original) A method according to claim 1, wherein said electric field is applied for substantially all of a duration of a glucose absorption event.

17. (Original) A method according to claim 1, wherein said electric field is applied prior to an expected glucose ingestion event.

18. (Original) A method according to claim 1, comprising triggering said electric field by a glucose ingestion event.

19. (Original) A method according to claim 1, wherein said electric field is applied irrespectively of an ingestion event.

20. (Original) A method according to claim 1, wherein said electric field is applied at least part of the time irrespectively of a blood glucose level.

21. (Original) A method according to claim 1, wherein said electric field is applied continuously for at least 24 hours.

22. (Original) A method according to claim 1, wherein said electric field is applied for a period of at least 15 minutes without sensing of its effect.

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23. (Original) A method according to claim 1, wherein said electric field is of a magnitude and temporal extent so that it does not significantly change blood insulin and glucose levels in the absence of an ingestion event.

24. (Original) A method according to claim 1, wherein said electric field reduces blood glucose levels by at least 20% of an elevation of the glucose level above a fasting baseline glucose level.

25. (Original) A method according to claim 1, wherein said electric field does not increase blood insulin levels, as measured by an average over five minutes, by more than 20%.

26. (Original) A method according to claim 1, comprising, delaying a gastric emptying by applying a treatment to the stomach.

27. (Original) A method according to claim 1, wherein said electric field is operative to delay a glucose peak at least by a duration of its application.

28. (Original) A method according to claim 1, wherein said electric field is operative to delay a glucose peak at least by 10 minutes.

29. (Original) A method according to claim 1, wherein said electric field is operative to delay an insulin peak at least by 10 minutes.

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30. (Currently Amended) A method of glucose level control, comprising:

providing at least one implanted electrode adapted to apply an electric field to affect a pancreas; and

applying an electric field to affect the pancreas operative to reduce blood glucose levels if elevated and not significantly reduce such levels if not substantially elevated.

31. (Original) A method according to claim 30, wherein said electric field reduces elevated glucose levels by at least 20%.

32. (Original) A method according to claim 30, wherein said electric field does not reduce unelevated glucose levels by more than 10%

33. (Original) A method according to claim 30, wherein said electric field does not impair exocrine functions of said pancreas.

34. (Currently amended) Apparatus for blood glucose control, comprising:

at least one implanted electrode ~~adapted to for~~ applying an electric field to affect a pancreas; and

circuitry ~~adapted to for electrify~~ electrifying said at least one implanted electrode ~~and configured to electrify said electrode~~ in a manner which compensates for a loss of acute response to a glucose ingestion event by said pancreas, wherein said circuitry reduces or prevents a substantial increase in insulin secretion during said compensation.

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35. (Original) Apparatus according to claim 34, wherein said circuitry compensates by causing the secretion of an insulin bolus.

36. (Original) Apparatus according to claim 34, wherein said circuitry compensates by reducing glucose levels in a non-insulin manner.

37. (Original) Apparatus according to claim 36, wherein said circuitry compensates by reducing glucagon secretion.

38. (Cancelled).

39. (Original) Apparatus according to claim 34, wherein for at least 20% of ingestion events said circuitry applies only an acute control of insulin levels.

40. (Original) Apparatus according to claim 39, wherein said apparatus is programmed with a knowledge of a slow acting chemical-based insulin therapy provided to said pancreas.

41. (Original) Apparatus according to claim 34, comprising an automatic ingestion sensor for automatically detecting an ingestion event.

42. (Original) Apparatus according to claim 34, comprising an automatic glucose sensor for automatically detecting a situation requiring an acute response.

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43. (Original) Apparatus according to claim 34, comprising an automatic glucose sensor for automatically detecting a situation requiring an acute insulin response.

44. (Original) Apparatus according to claim 34, wherein said response is an acute insulin response.

45 - 48. (Cancelled).

49. (Currently Amended) Apparatus for blood glucose control, comprising:

at least one implanted electrode adapted to apply an electric field to affect pancreatic tissue; and

circuitry adapted to electrify said at least one implanted electrode ~~and configured to electrify said electrode~~ in a manner which reduces glucose levels and does not substantially elevate insulin levels above a baseline value, when glucose levels are elevated.

50. (Original) Apparatus according to claim 49, wherein said circuitry is a closed loop system including sensing of the effect of the electrification and wherein said circuitry is configured to over stimulate in cases of doubt.

51. (Original) Apparatus according to claim 49, wherein said circuitry is a semi-open loop system where a relatively long stimulation series is applied without feedback.

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52. (Original) Apparatus according to claim 49, wherein said circuitry is an open loop system where a stimulation series is applied responsive to a trigger and without feedback.

53. (Original) Apparatus according to claim 49, wherein said circuitry applies a constant voltage field.

54. (Original) Apparatus according to claim 49, wherein said circuitry applies a constant current field.

55. (Original) Apparatus according to claim 49, wherein said pancreatic tissue comprises an in-vivo pancreas.

56. (Original) Apparatus according to claim 49, wherein said pancreatic tissue comprises a pancreatic tissue implant.

57-60. (Cancelled).

61. (Currently Amended) A method of controlling blood glucose, the method comprising:

providing at least one implanted electrode;

providing a fixed protocol; and

electrifying said at least one implanted electrode to apply electric field to affect a pancreas in accordance with said fixed protocol,  
wherein said electrifying comprises electrifying irrespective of blood glucose level.



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62. (Currently Amended) A method according to claim 58, wherein said fixed protocol comprises electrifying said at least one implanted electrode to provide a pulse series without synchronizing said pulse series to pancreatic activity.

63. (Currently Amended) A method according to claim 58, wherein said fixed protocol comprises electrifying said at least one implanted electrode to provide a pulse series irrespectively of an ingestion event.

64. (Previously Presented) A method according to claim 58, wherein pancreatic electrical activity is not measured during said electrifying.

65. (Previously Presented) A method according to claim 58, wherein said fixed protocol comprises periodic application of a pulse series.

66. (Previously Presented) A method according to claim 58, wherein said electric field is repeated for a period of less than 30 minutes.

67. (Previously Presented) A method according to claim 58, wherein said electric field is repeated for a period of between 30 and 180 minutes.